

that assures that the required authority and organizational freedom, including sufficient independence from cost and schedule, when opposed to safety considerations, are provided.

(e) Because of the many variables involved, such as the number of personnel, the type of activity being performed, and the location or locations where activities are performed, the organizational structure for executing the quality assurance program may take various forms, provided that the persons and organizations assigned the quality assurance functions have the required authority and organizational freedom.

(f) Irrespective of the organizational structure, the individual(s) assigned the responsibility for assuring effective execution of any portion of the quality assurance program, at any location where activities subject to this section are being performed, must have direct access to the levels of management necessary to perform this function.

#### **§ 71.105 Quality assurance program.**

(a) The licensee shall establish, at the earliest practicable time consistent with the schedule for accomplishing the activities, a quality assurance program that complies with the requirements of §§ 71.101 through 71.137. The licensee shall document the quality assurance program by written procedures or instructions and shall carry out the program in accordance with those procedures throughout the period during which the packaging is used. The licensee shall identify the material and components to be covered by the quality assurance program, the major organizations participating in the program, and the designated functions of these organizations.

(b) The licensee, through its quality assurance program, shall provide control over activities affecting the quality of the identified materials and components to an extent consistent with their importance to safety, and as necessary to assure conformance to the approved design of each individual package used for the shipment of radioactive material. The licensee shall assure that activities affecting quality are accomplished under suitably controlled conditions. Controlled condi-

tions include the use of appropriate equipment; suitable environmental conditions for accomplishing the activity, such as adequate cleanliness; and assurance that all prerequisites for the given activity have been satisfied. The licensee shall take into account the need for special controls, processes, test equipment, tools, and skills to attain the required quality, and the need for verification of quality by inspection and test.

(c) The licensee shall base the requirements and procedures of its quality assurance program on the following considerations concerning the complexity and proposed use of the package and its components:

- (1) The impact of malfunction or failure of the item to safety;
- (2) The design and fabrication complexity or uniqueness of the item;
- (3) The need for special controls and surveillance over processes and equipment;
- (4) The degree to which functional compliance can be demonstrated by inspection or test; and
- (5) The quality history and degree of standardization of the item.

(d) The licensee shall provide for indoctrination and training of personnel performing activities affecting quality, as necessary to assure that suitable proficiency is achieved and maintained. The licensee shall review the status and adequacy of the quality assurance program at established intervals. Management of other organizations participating in the quality assurance program shall review regularly the status and adequacy of that part of the quality assurance program which they are executing.

#### **§ 71.107 Package design control.**

(a) The licensee shall establish measures to assure that applicable regulatory requirements and the package design, as specified in the license for those materials and components to which this section applies, are correctly translated into specifications, drawings, procedures, and instructions. These measures must include provisions to assure that appropriate quality standards are specified and included in design documents and that deviations from standards are controlled.